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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,223	07/11/2003	Eric K. Mangiardi	000100.0015	4411

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EXAMINER	
MARMOR II, CHARLES ALAN	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,223	MANGIARDI ET AL.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,10-24,37 and 39-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,10-24,37 and 39-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 20, 2006 has been entered.

The Examiner acknowledges the amendments to claims 1, 6, 7, 13, 24, 37 and 42, as well as the addition of New claim 43. Claims 1, 3-8, 10-24, 37 and 39-43 are pending.

Drawings

2. The drawings were received on January 20, 2006. These drawings are acceptable.

Claim Objections

3. Claim 24 is objected to because of the following informalities: at line 3, "on" should read --an--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 5-7, 10, 12, 13, 37, 39, 41 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Hasson ('732). Hasson teaches a measuring device that is capable of allowing a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the same exploratory procedure. The device (10) includes an exterior conduit (68) having measurement markers (70) formed on a portion thereof; an interior conduit (58) slidably disposed within the exterior conduit and having a depth marking mechanism (72) which may be visible through a portion of the exterior conduit (see at least Figures 2 and 3); a measurement assembly including a plurality of legs (26) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (30) operatively connected with the measurement assembly. The handle includes means for opening and closing (42) the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration. Inward facing surfaces of the legs (26) are substantially in flush contact with one another along the length thereof at slit (24) when the measurement assembly is in a closed position. The distal ends of the legs are coupled together and the measurement of the target site takes place between the proximal and the distal ends of the legs (see at least Figure 3). Given that the diameter of the measurement assembly is known in both the open and closed configurations (see Figures 3 and 2, respectively), the handle further includes a measurement indicator (38), wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between the first and second handle locations. In operation, the device is introduced into an

appropriate anatomical orifice of a patient; delivered adjacent a target segment of a lumen within the patient; and the length of the target segment is measured within the patient.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 3-8, 10-24, 37 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain ('147) in view of Colvin et al. ('892).

Jain teaches a body lumen measuring device that is capable of allowing a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the same exploratory procedure. The device (10) includes an exterior conduit (22); an interior conduit (24) slidably disposed within the exterior conduit and having a depth marking mechanism (42); a measurement assembly (26 or 54) including a plurality of legs (44 or 56, 58) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (24, 30) operatively connected with the measurement assembly. The handle includes means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration. The inward facing surfaces along a portion of the legs are in flush contact with one another along a portion distal of the proximal ends when the measurement assembly is closed (see Figures 2 and 5). The legs form an acute angle with respect to one

another as the measurement assembly is moved distally in relation to the first conduit (see Figures 3 and 6). The handle further includes the measurement indicator, wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between the first and second handle locations. The device is used to measure a target segment of a lumen of a patient so as to select a suitable interventional prosthesis. In operation, the device is introduced into an appropriate anatomical orifice of a patient; delivered adjacent a target segment of a lumen within the patient; and the length or diameter of the target segment is measured within the patient. Jain teaches all of the limitations of the claims except that the exterior conduit has measurement markers formed on a portion thereof and that the depth markings on the interior conduit are visible through the exterior conduit.

Colvin et al. teach a body lumen measuring device that is capable of allowing a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the same exploratory procedure. The device (10) includes an exterior conduit (12) having measurement markers (24) formed on a portion thereof; an interior conduit (16) slidably disposed within the exterior conduit and having a depth marking mechanism (22) which may be visible through a portion of the exterior conduit (20); a measurement assembly including a plurality of legs (54a-54c) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (14) operatively connected with the measurement assembly. The handle includes means for opening and closing the measurement assembly (18) by actuating the handle along a continuum between a first closed configuration and a second open configuration. The legs form an acute angle with respect to one another as the measurement assembly is moved distally in relation to the first conduit. The

handle further includes the measurement indicator, wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between the first and second handle locations. The device is used to measure a target segment of a lumen of a patient so as to select a suitable interventional prosthesis. In operation, the device is introduced into an appropriate anatomical orifice of a patient; delivered adjacent a target segment of a lumen within the patient; and the length of the target segment is measured within the patient. An optical endoscope may be operatively coupled therewith, so that the measuring step may be accomplished using the optical endoscope. The device may be used to measure the diameter and length of a stenotic target segment of the lumen within the patient, including the height and length of the stenosis.

Applicant has not disclosed that using a measurement indicator arrangement having a plurality of measurement markers formed on a portion of the exterior conduit and a depth marking mechanism on the interior conduit that is visible through a portion of the exterior conduit solves any stated problem or is for any particular purpose. Moreover, it appears that the measurement indicator arrangement of Jain, or applicant's invention, would perform equally well with the plurality of measurement markers formed on a portion of the exterior conduit and a depth marking mechanism on the interior conduit that is visible through a portion of the exterior conduit, similar to the arrangement taught by Colvin et al. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Jain to include a measurement indicator arrangement similar to that of Colvin et al, because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Jain.

Response to Arguments

8. Applicant's arguments, filed January 20, 2006, with respect to the rejection of claims 1-3, 6-8, 10, 13, 37, 39 and 42 under 35 U.S.C. 102(e) as being anticipated by Matthews et al. ('351) and the rejection of claims 1-4, 6-8, 10, 11, 13-23, 37, 39 and 42 under 35 U.S.C. 102(b) as being anticipated by Colvin et al. ('892) have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, a new grounds of rejection is made in view of Hasson ('732) which teaches a measurement assembly having a pair of legs with inward facing surfaces that are in flush contact with one another along at least a portion of the inward facing surfaces distal to the proximal ends of the legs.

9. Applicant's arguments filed January 20, 2006 with respect to the rejections under 35 U.S.C. 103(a) as being unpatentable over Colvin et al. ('892) in view of Jain ('147) have been fully considered but they are not fully persuasive.

Applicant contends that Jain and Colvin et al. both fail to teach or fairly suggest a measurement assembly having inward facing surfaces in flush contact with one another along at least a portion of the inward facing surfaces distal of the proximal ends of the legs. The Examiner respectfully disagrees. While the Examiner concedes that neither Jain nor Colvin et al. teach an arrangement where the entire length of the inward facing surfaces of the legs are in flush contact as recited in claim 43, the Examiner contends that at least a portion of the inward facing surfaces distal of the proximal ends of the legs are in flush contact in at least Jain when the measurement assembly is closed. The Examiner notes that the "proximal end" of the legs

may be considered to be the terminal point at the proximal-most end of each leg. Broadly interpreted, a portion distal to the proximal end of the legs may be considered to be a point distal, but immediately adjacent, thereto. This limitation does not require that the portion be a substantial length of the legs. In view of the foregoing, the Examiner respectfully submits that at least Jain teaches that a portion of the inward facing surfaces distal of the proximal ends of the legs are in flush contact when the measurement assembly is closed. While Applicant has previously argued that the legs of Jain are fanned out when the measurement assembly is in the closed position, the Examiner respectfully submits that Figure 2 of the Jain patent shows that the inward facing surfaces of the proximal ends of legs are forced into flush contact prior to fanning out at a more distal portion thereof. The Examiner believes this position is supported by the fact that the disclosure of Jain suggests that the sensor 26 is not moveable with respect to the catheter 24 (see column 3, lines 2-12), and that the outwardly biased sensor filaments 44 do not begin to fan outward immediately from the point where the sensor is secured to the distal end of the catheter. With respect to the embodiment illustrated in Figures 5 and 6 of Jain, the Examiner respectfully submits that the inward facing surfaces of the legs are continuously in flush contact with one another at the distal-most ends thereof where the legs 56, 58 are secured together.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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March 9, 2006